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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,868	12/11/2003	Randy Westlund	GUID.076PA (02-046)	8097
7590		07/15/2004	EXAMINER	
Crawford Maunu PLLC		MACHUGA, JOSEPH S		
Suite 390		ART UNIT		
1270 Northland Drive		PAPER NUMBER		
St. Paul, MN 55120		3762		

DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/733,868

Applicant(s)

WESTLUND, RANDY

Examiner

Joseph S. Machuga

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the passive fixation device of and the tines must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 11 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification lacks support for the passive fixation arrangement and the timed fixation arrangement.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3, 6, 8, 12, 14, 16, 19, 21, 30, 31 and 33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Helland et al 5545201.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2, 4, 7, 9, 15, 17, 20, 22, 32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helland et al #5545201 in view of Carson #5931862.

5. Helland et al discloses an electrode assembly (50+) having a PTFE coating 48. The reference teaches (column 4, lines 52+) that this member can include a microporous coating. Carson teaches that ePTFE is a useful microporous material in the medical leads. Given this teaching it would have been obvious to use ePTFE to coat member 50 in Helland et al's electrode assembly given Helland's teaching that such a porous coating is desirable and Carson's teaching the ePTFE is desirable to coat a medical lead.

Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rockland et al #4010758 in view of Helland et al #5545201.

Rockland discloses a medical lead assembly having a helical electrode covered with an biocompatible material (17). Helland et al teaches that PTFE is a biocompatible material useful in medical leads. Given Helland et al's teaching it would have been obvious to one of ordinary skill in the art to PTFE in Rockland et al helical electrode to provide an inert biocompatible coating.

Claims 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al #5845396 in view of Helland et al #5545201.

Altman et al discloses an electrode assembly have all the claimed features except the coating on the tines. Helland et al teaches adding a coating of PTFE on a fixing member to provide a biocompatible electrode assembly. Given this teaching it would have been obvious to one of ordinary skill in the art to add a coating of PTFE to Altman et al's fixing device to provide a biocompatible assembly.

6. Claims 5, 10, 18, 23 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helland et al #5545201 in view of Stokes et al H356.

7. Helland et al discloses an electrode assembly for the heart having all the claimed features except the steroid eluting component.

8. Stokes discloses an heart implant. The reference teaches adding an steroid eluting port. This helps eliminate the effects of tissue reaction to the electrode.

9. It would have been obvious to one of ordinary skill in the art to a steroid feed to Helland et al's electrode assembly to eliminate the effects of tissue reaction given Stokes teaching of this.

10. Claims 24, 25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dutcher et al #4357946 in view of Helland et al #5545201.

Dutcher et al discloses an electrode assembly that implants externally of the heart. The device is attached to the heart muscle through a helical electrode. Helland et al discloses an electrode assembly having insulating covers 48, 50+ of PTFE. The reference teaches (column 4, lines 52+) that this member can further include a microporous coating. Given these teachings, it would have been obvious to one of ordinary skill in the art to use an electrode assembly of the type disclosed by Helland et al to provide a biocompatible lead assembly having greater sensitivity in place of the electrode assembly in Dutcher et al's device.

11. Claims 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dutcher et al #4357946 in view of Helland et al #5545201 as applies to claim 24 above in further view of Carson #5931862.

12. Carson teaches that ePTFE is a useful microporous material in the medical leads. Given this teaching it would have been obvious to use ePTFE to coat member 50 in Helland et al's electrode assembly of the proposed combination given Helland's teaching that such a porous coating is desirable and Carson's teaching the ePTFE is desirable in a medical lead.

13. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dutcher et al #4357946 in view of Helland et al #5545201 as applied to claim 24 above in further view of Stokes et al H356.

14. Stokes discloses an heart implant. The reference teaches adding an steroid eluting port. This helps eliminate the effects of tissue reaction to the electrode.

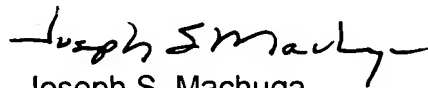
15. It would have been obvious to one of ordinary skill in the art to a steroid feed to the electrode assembly of the proposed combination to eliminate the effects of tissue reaction given Stokes teaching of this.

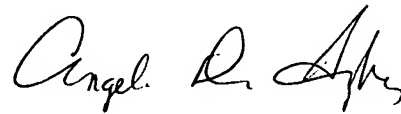
16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on Monday-Friday; 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Joseph S. Machuga
Examiner
Art Unit 3762


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